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BRINKS HOFER GILSON & LIONE
P.O. BOX 10395
CHICAGO, IL 60610

EXAMINER	
HAUTH, GALEN H	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/813,415	BOATMAN ET AL.	
	Examiner	Art Unit	
	GALEN HAUTH	1791	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3,5-8,10-23 and 25-41* is/are pending in the application.

4a) Of the above claim(s) *21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3, 5-8,10-16, 18, 20, 22, 23 and 25-41* is/are rejected.

7)☒ Claim(s) *17,19 and 36* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *01/21/2009, 04/16/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Claim 21, originally withdrawn, was previously indicated as rejoined due to be dependent on an allowable claim. The allowability of the independent claim has been withdrawn and as such the status of Claim 21 remains withdrawn as well according to the original election.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 3, 16, 25, 28-35, 37, 38, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaldany (PN 5222949) in view of O'Neil et al. (PN 5998551).

a. With regards to claim 3, Kaldany teaches a method of forming a catheter with varying durometer (abstract) continuously formed by subjecting portions of

the catheter to radiation (col 5 ln 1-6). Kaldany does not teach a polyamide material.

b. O'Neil teaches a nylon block copolymer of polyamide and elastomer that cross links when subjected to irradiation, which improves mechanical properties, useful in the medical industry (abstract). O'Neil teaches the formation of a catheter with varying durometer through the irradiation (col 4 ln 35-42). O'Neil teaches the inclusion of a cross linking promoter of triallylcyanurate (TAC) or triallylisocyanurate (TAIC) in an amount of 2% by weight (col 4 ln 15-17, col 3 ln 38-41). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the nylon block copolymer of O'Neil in the process of Kaldany, because both relate to the formation of varying durometer catheters and O'Neil teaches that the material is advantageous for rigid/flex catheters (col 4 ln 49-55). O'Neil teaches that the material has a variety of ratios between polyether and polyamide blocks (col 3 ln 28-31) but does not explicitly state a ratio of 3:1 (25% nylon) or greater. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a copolymer of ratio 3:1 or greater as O'Neil teaches that multiple varieties exist presenting differing mechanical properties, thus one of ordinary skill in the art would have been motivated to use ratios of 3:1 or greater through optimization of the mechanical properties of the catheter as the ratio is a result effective variable.

c. With regards to claim 16, Kaldany teaches a method of forming a catheter with varying durometer (abstract) continuously formed by subjecting portions of

the catheter to radiation (col 5 ln 1-6). With regards to the limitation of a continuously varied amount of radiation applied to a transition region between two points on the catheter, the catheter of Kaldany has a continuously alternated pattern between the two ends of the catheter, thus defining the proximal and distal portions as first and second parts leaving the alternating and continuously varied portions between them as a transition region. Kaldany does not teach a polyamide material.

d. O'Neil teaches a nylon block copolymer of polyamide and elastomer that cross links when subjected to irradiation, which improves mechanical properties, useful in the medical industry (abstract). O'Neil teaches the formation of a catheter with varying durometer through the irradiation (col 4 ln 35-42). O'Neil teaches the inclusion of a cross linking promoter of triallylcyanurate (TAC) or triallylisocyanurate (TAIC) in an amount of 2% by weight (col 4 ln 15-17, col 3 ln 38-41). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the nylon block copolymer of O'Neil in the process of Kaldany, because both relate to the formation of varying durometer catheters and O'Neil teaches that the material is advantageous for rigid/flex catheters (col 4 ln 49-55).

e. With regards to claim 25, Kaldany teaches a method of forming a catheter with varying durometer (abstract) continuously formed by subjecting portions of the catheter to radiation (col 5 ln 1-6). Kaldany does not teach a polyamide material.

f. O'Neil teaches a nylon block copolymer of polyamide and elastomer that cross links when subjected to irradiation, which improves mechanical properties, useful in the medical industry (abstract). O'Neil teaches the formation of a catheter with varying durometer through the irradiation (col 4 ln 35-42). O'Neil teaches the inclusion of a cross linking promoter of triallylcyanurate (TAC) or triallylisocyanurate (TAIC) in an amount of 2% by weight (col 4 ln 15-17, col 3 ln 38-41). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the nylon block copolymer of O'Neil in the process of Kaldany, because both relate to the formation of varying durometer catheters and O'Neil teaches that the material is advantageous for rigid/flex catheters (col 4 ln 49-55). O'Neil teaches a difference in mechanical properties based on the amount of radiation delivered to the material (Table 1), so it would have been obvious to one of ordinary skill in the art at the time the invention was made to use different amounts of radiation to achieve different durometers in the catheter of Kaldany, as the method achieves similar results presenting a reasonable expectation of success.

g. With regards to claim 28, Kaldany teaches a method of forming a catheter with varying durometer (abstract) continuously formed by subjecting portions of the catheter to radiation (col 5 ln 1-6). Kaldany does not teach a polyamide material.

h. O'Neil teaches a nylon block copolymer of polyamide and elastomer that cross links when subjected to irradiation, which improves mechanical properties,

useful in the medical industry (abstract). O'Neil teaches the formation of a catheter with varying durometer through the irradiation (col 4 ln 35-42). O'Neil teaches the inclusion of a cross linking promoter of triallylcyanurate (TAC) or triallylisocyanurate (TAIC) in an amount of 2% by weight (col 4 ln 15-17, col 3 ln 38-41). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the nylon block copolymer of O'Neil in the process of Kaldany, because both relate to the formation of varying durometer catheters and O'Neil teaches that the material is advantageous for rigid/flex catheters (col 4 ln 49-55). With regards to the limitation of the promoter being added in an amount sufficient to produce a product of generally about equal strength to a product comparably cross linked, the promoter effects the rate of polymerization, and thus a similar product comparably cross linked would inherently have generally about equal strength as both are generally the same composition with comparable cross linking.

i. With regards to claim 29, Kaldany teaches a method of forming a catheter with varying durometer (abstract) continuously formed by subjecting portions of the catheter to ultraviolet radiation (col 5 ln 1-6). Kaldany does not teach a polyamide material.

j. O'Neil teaches a nylon block copolymer of polyamide and elastomer that cross links when subjected to irradiation, which improves mechanical properties, useful in the medical industry (abstract). O'Neil teaches the formation of a catheter with varying durometer through the irradiation (col 4 ln 35-42). O'Neil

teaches the inclusion of a cross linking promoter of triallylcyanurate (TAC) or triallylisocyanurate (TAIC) in an amount of 2% by weight (col 4 ln 15-17, col 3 ln 38-41). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the nylon block copolymer of O'Neil in the process of Kaldany, because both relate to the formation of varying durometer catheters and O'Neil teaches that the material is advantageous for rigid/flex catheters (col 4 ln 49-55).

k. With regards to claim 30, Kaldany teaches a method of forming a catheter with varying durometer (abstract) continuously formed by subjecting portions of the catheter to radiation (col 5 ln 1-6). Kaldany does not teach a polyamide material.

l. O'Neil teaches a nylon block copolymer of polyamide and elastomer that cross links when subjected to irradiation, which improves mechanical properties, useful in the medical industry (abstract). O'Neil teaches the formation of a catheter with varying durometer through the irradiation (col 4 ln 35-42). O'Neil teaches the inclusion of a cross linking promoter of triallylcyanurate (TAC) or triallylisocyanurate (TAIC) in an amount of 2% by weight (col 4 ln 15-17, col 3 ln 38-41). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the nylon block copolymer of O'Neil in the process of Kaldany, because both relate to the formation of varying durometer catheters and O'Neil teaches that the material is advantageous for rigid/flex catheters (col 4 ln 49-55). O'Neil teaches subjecting the material to preferably 5 megarads of

radiation (col 4 ln 8-14). It would have been obvious to one of ordinary skill in the art at the time the invention was made to subject the material to 5 megarads of radiation as O'Neil teaches this is a beneficial amount for optimum mechanical performance.

m. With regards to claim 31, Kaldany teaches a method of forming a catheter with varying durometer (abstract) continuously formed by subjecting portions of the catheter to radiation (col 5 ln 1-6). Kaldany does not teach a polyamide material.

n. O'Neil teaches a nylon block copolymer of polyamide and elastomer that cross links when subjected to irradiation, which improves mechanical properties, useful in the medical industry (abstract). O'Neil teaches the formation of a catheter with varying durometer through the irradiation (col 4 ln 35-42). O'Neil teaches the inclusion of a cross linking promoter of triallylcyanurate (TAC) or triallylisocyanurate (TAIC) in an amount of 2% by weight (col 4 ln 15-17, col 3 ln 38-41). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the nylon block copolymer of O'Neil in the process of Kaldany, because both relate to the formation of varying durometer catheters and O'Neil teaches that the material is advantageous for rigid/flex catheters (col 4 ln 49-55). O'Neil and Kaldany do not teach a specific method for the mixing of the reactant and the reaction promoter; however, it would have been obvious to one of ordinary skill in the art at the time the invention was made to compound the polymer with the reaction promoter as O'Neil and Kaldany do not teach a

specific mixing method leaving one of ordinary skill in the art to look to known mixing methods.

o. With regards to claim 32, Kaldany teaches a method of forming a catheter with varying durometer (abstract) continuously formed by subjecting portions of the catheter to radiation (col 5 ln 1-6) after extrusion (col 5 ln 25-30). Kaldany does not teach a polyamide material.

p. O'Neil teaches a nylon block copolymer of polyamide and elastomer that cross links when subjected to irradiation, which improves mechanical properties, useful in the medical industry (abstract). O'Neil teaches the formation of a catheter with varying durometer through the irradiation (col 4 ln 35-42). O'Neil teaches the inclusion of a cross linking promoter of triallylcyanurate (TAC) or triallylisocyanurate (TAIC) in an amount of 2% by weight (col 4 ln 15-17, col 3 ln 38-41). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the nylon block copolymer of O'Neil in the process of Kaldany, because both relate to the formation of varying durometer catheters and O'Neil teaches that the material is advantageous for rigid/flex catheters (col 4 ln 49-55).

q. With regards to claim 33, Kaldany teaches a method of forming a catheter with varying durometer (abstract) continuously formed by subjecting portions of the catheter to radiation (col 5 ln 1-6). Kaldany does not teach a polyamide material.

r. O'Neil teaches a nylon block copolymer of polyamide and elastomer that cross links when subjected to irradiation, which improves mechanical properties, useful in the medical industry (abstract). O'Neil teaches the formation of a catheter with varying durometer through the irradiation (col 4 ln 35-42). O'Neil teaches the inclusion of a cross linking promoter of triallylcyanurate (TAC) or triallylisocyanurate (TAIC) in an amount of 2% by weight (col 4 ln 15-17, col 3 ln 38-41). O'Neil teaches the use of polyether amides (col 3 ln 21-22). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the nylon block copolymer of O'Neil in the process of Kaldany, because both relate to the formation of varying durometer catheters and O'Neil teaches that the material is advantageous for rigid/flex catheters (col 4 ln 49-55).

s. With regards to claims 34 and 35, O'Neil teaches using a polyether amide of polyether blocks separated by nylon components (col 3 ln 20-30).

t. With regards to claim 37, Kaldany teaches a method of forming a catheter with varying durometer (abstract) continuously formed by subjecting portions of the catheter to radiation (col 5 ln 1-6). Kaldany does not teach a polyamide material.

u. O'Neil teaches a nylon block copolymer of polyamide and elastomer that cross links when subjected to irradiation, which improves mechanical properties, useful in the medical industry (abstract). O'Neil teaches the formation of a catheter with varying durometer through the irradiation (col 4 ln 35-42). O'Neil teaches the inclusion of a cross linking promoter of triallylcyanurate (TAC) or

triallylisocyanurate (TAIC) in an amount of 2% by weight (col 4 ln 15-17, col 3 ln 38-41). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the nylon block copolymer of O'Neil in the process of Kaldany, because both relate to the formation of varying durometer catheters and O'Neil teaches that the material is advantageous for rigid/flex catheters (col 4 ln 49-55).

v. With regards to claim 38, O'Neil teaches that the material has a variety of ratios between polyether and polyamide blocks (col 3 ln 28-31) but does not explicitly state a ratio of 3:1 (25% nylon) or greater. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a copolymer of ratio 3:1 or greater as O'Neil teaches that multiple varieties exist presenting differing mechanical properties, thus one of ordinary skill in the art would have been motivated to use ratios of 3:1 or greater through optimization of the mechanical properties of the catheter as the ratio is a result effective variable.

w. With regards to claim 41, Kaldany teaches a method of forming a catheter with varying durometer (abstract) continuously formed by subjecting portions of the catheter to radiation (col 5 ln 1-6) after extrusion (col 5 ln 25-30). Kaldany does not teach a polyamide material.

x. O'Neil teaches a nylon block copolymer of polyamide and elastomer that cross links when subjected to irradiation, which improves mechanical properties, useful in the medical industry (abstract). O'Neil teaches the formation of a

catheter with varying durometer through the irradiation (col 4 ln 35-42). O'Neil teaches the inclusion of a cross linking promoter of triallylcyanurate (TAC) or triallylisocyanurate (TAIC) in an amount of 2% by weight (col 4 ln 15-17, col 3 ln 38-41). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the nylon block copolymer of O'Neil in the process of Kaldany, because both relate to the formation of varying durometer catheters and O'Neil teaches that the material is advantageous for rigid/flex catheters (col 4 ln 49-55). O'Neil teaches that the material has a variety of ratios between polyether and polyamide blocks (col 3 ln 28-31) but does not explicitly state a ratio of 9:1 (10% nylon). However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a copolymer of ratio 9:1 as O'Neil teaches that multiple varieties exist presenting differing mechanical properties, thus one of ordinary skill in the art would have been motivated to use ratios of 9:1 through optimization of the mechanical properties of the catheter as the ratio is a result effective variable. O'Neil teaches subjecting the material to preferably 5 megarads of radiation (col 4 ln 8-14). It would have been obvious to one of ordinary skill in the art at the time the invention was made to subject the material to 5 megarads of radiation as O'Neil teaches this is a beneficial amount for optimum mechanical performance. O'Neil and Kaldany do not teach a specific method for the mixing of the reactant and the reaction promoter; however, it would have been obvious to one of ordinary skill in the art at the time the invention was made to compound the polymer with the reaction promoter as

O'Neil and Kaldany do not teach a specific mixing method leaving one of ordinary skill in the art to look to known mixing methods. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use **about** 3% reaction promoter as O'Neil teaches using 2% and one of ordinary skill in the art would vary the amount of reaction promoter to effectively change the cross linking rate as the reaction promoter weight percentage is a result effective variable altering the rate at which the reaction takes place.

5. Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaldany (PN 5222949) in view of O'Neil et al. (PN 5998551) and Wang et al. (PN 5807520).

a. With regards to claim 5, Kaldany teaches a method of forming a catheter with varying durometer (abstract) continuously formed by subjecting portions of the catheter to radiation (col 5 ln 1-6) after extrusion (col 5 ln 25-30). Kaldany does not teach a polyamide material or the integral forming of a balloon portion.

b. O'Neil teaches a nylon block copolymer of polyamide and elastomer that cross links when subjected to irradiation, which improves mechanical properties, useful in the medical industry (abstract). O'Neil teaches the formation of a catheter with varying durometer through the irradiation (col 4 ln 35-42). O'Neil teaches the inclusion of a cross linking promoter of triallylcyanurate (TAC) or triallylisocyanurate (TAIC) in an amount of 2% by weight (col 4 ln 15-17, col 3 ln 38-41). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the nylon block copolymer of O'Neil in the process

of Kaldany, because both relate to the formation of varying durometer catheters and O'Neil teaches that the material is advantageous for rigid/flex catheters (col 4 ln 49-55).

c. Wang teaches a method for forming a balloon for a catheter from an extruded piece of tubing (abstract). Wang teaches that the balloon catheters formed from this method produce a smaller balloon thickness providing easier insertion into the body (col 11 ln 45-49). It would have been obvious for one of ordinary skill in the art at the time the invention was made to use a portion of the catheter produced by Kaldany for a balloon as taught by Wang, because doing so results in an improved balloon catheter.

d. With regards to claim 6, Wang teaches applying heat and pressure to shape the balloon (col 8 ln 16-60).

6. Claims 7-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaldany (PN 5222949) in view of O'Neil et al. (PN 5998551) and Weldon (PN 5088991).

a. With regards to claims 7 and 8, Kaldany teaches a method of forming a catheter with varying durometer (abstract) continuously formed by subjecting portions of the catheter to radiation (col 5 ln 1-6) after extrusion (col 5 ln 25-30). Kaldany does not teach a polyamide material or the integral forming of a pigtail portion.

b. O'Neil teaches a nylon block copolymer of polyamide and elastomer that cross links when subjected to irradiation, which improves mechanical properties, useful in the medical industry (abstract). O'Neil teaches the formation of a

catheter with varying durometer through the irradiation (col 4 ln 35-42). O'Neil teaches the inclusion of a cross linking promoter of triallylcyanurate (TAC) or triallylisocyanurate (TAIC) in an amount of 2% by weight (col 4 ln 15-17, col 3 ln 38-41). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the nylon block copolymer of O'Neil in the process of Kaldany, because both relate to the formation of varying durometer catheters and O'Neil teaches that the material is advantageous for rigid/flex catheters (col 4 ln 49-55).

c. Weldon teaches forming a pigtail curl structure on a fuseless elongated polymer tube catheter (col 3 ln 56-65) made from nylon material (col 5 ln 1-10) as a pigtail structure is a desired shape of catheter in the art (col 3 ln 65-col 4 ln 4). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a pigtail structure in the forming process as taught by Weldon in the process of Kaldany as such is a desired shape of catheter in the art as taught by Weldon, and both relate to polyamide catheter formation providing a reasonable expectation of success.

d. With regards to claim 10, O'Neil teaches that the material cross links upon radiation (col 4 ln 35-42).

e. With regards to claim 11, O'Neil teaches a difference in mechanical properties based on the amount of radiation delivered to the material (Table 1), so it would have been obvious to one of ordinary skill in the art at the time the invention was made to use different amounts of radiation to achieve different

durometers in the catheter of Kaldany, as the method achieves similar results presenting a reasonable expectation of success.

f. With regards to claim 12, Kaldany teaches forming a catheter (abstract) which inherently posses a tip and a body as a catheter has a finite end.

g. With regards to claims 13 and 14, O'Neil teaches a difference in mechanical properties based on the amount of radiation delivered to the material (Table 1), so it would have been obvious to one of ordinary skill in the art at the time the invention was made to use different amounts of radiation to achieve different durometers in the catheter of Kaldany, as the method achieves similar results presenting a reasonable expectation of success.

7. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaldany (PN 5222949) in view of O'Neil et al. (PN 5998551) and Weldon (PN 5088991) as applied to claim 14 above, and further in view of Luther et al. (PN 6595954).

With regards to claim 15, Kaldany in view of O'Neil and Weldon, as applied to claim 14 above, teaches a method for forming a catheter of varying durometer with a catheter tip, but does not teach the fitting of a needle collar into a catheter tip. Luther teaches inclusion of a locking ring on a catheter needle for abutment with a projection in the tip of the catheter to limit movement of the needle (col 5 ln 34-40). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the needle locking ring mechanism of Luther in the process of Kaldany in view of O'Neil and Weldon, because doing so prevents

the accidental puncture of health care professionals and increases safety (col 1 ln 63-67)

8. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaldany (PN 5222949) in view of O'Neil et al. (PN 5998551) and Roberts (PN 4156538).

a. With regards to claim 18, Kaldany teaches a method of forming a catheter with varying durometer (abstract) continuously formed by subjecting portions of the catheter to radiation (col 5 ln 1-6) after extrusion (col 5 ln 25-30). Kaldany does not teach a polyamide material or an interior tubular element.

b. O'Neil teaches a nylon block copolymer of polyamide and elastomer that cross links when subjected to irradiation, which improves mechanical properties, useful in the medical industry (abstract). O'Neil teaches the formation of a catheter with varying durometer through the irradiation (col 4 ln 35-42). O'Neil teaches the inclusion of a cross linking promoter of triallylcyanurate (TAC) or triallylisocyanurate (TAIC) in an amount of 2% by weight (col 4 ln 15-17, col 3 ln 38-41). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the nylon block copolymer of O'Neil in the process of Kaldany, because both relate to the formation of varying durometer catheters and O'Neil teaches that the material is advantageous for rigid/flex catheters (col 4 ln 49-55).

c. Roberts teaches a method for irradiating a polymer in which portions of the product are cross linked and portions are not (col 1 ln 19-29). Roberts teaches that it was known in the art at the time the invention was made to use a

shield with selective areas removed to selectively irradiate product in a continuous process (col 3 ln 3-13). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a shield in the selective irradiation of Kaldany as taught by Roberts, because such is an art equivalent method for selective radiation of a continuous product presenting a reasonable expectation of success.

9. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaldany (PN 5222949) in view of O'Neil et al. (PN 5998551) and Macaulay et al. (PN 5234416).

a. With regards to claim 20, Kaldany teaches a method of forming a catheter with varying durometer (abstract) continuously formed by subjecting portions of the catheter to radiation (col 5 ln 1-6) after extrusion (col 5 ln 25-30). Kaldany does not teach a polyamide material or an interior tubular element.

b. O'Neil teaches a nylon block copolymer of polyamide and elastomer that cross links when subjected to irradiation, which improves mechanical properties, useful in the medical industry (abstract). O'Neil teaches the formation of a catheter with varying durometer through the irradiation (col 4 ln 35-42). O'Neil teaches the inclusion of a cross linking promoter of triallylcyanurate (TAC) or triallylisocyanurate (TAIC) in an amount of 2% by weight (col 4 ln 15-17, col 3 ln 38-41). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the nylon block copolymer of O'Neil in the process of Kaldany, because both relate to the formation of varying durometer catheters

and O'Neil teaches that the material is advantageous for rigid/flex catheters (col 4 ln 49-55).

c. Macaulay teaches a catheter with a lubricious liner interior (abstract) made of polytetrafluoroethylene or similar material known for its lubricity (39-45). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a lubricious liner in the catheter of Kaldany, because such was a known process in the art as taught by Macaulay and provides the benefit of a lubricious or non-stick lining to the catheter.

10. Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaldany (PN 5222949) in view of O'Neil et al. (PN 5998551) and Macaulay et al. (PN 5234416) as applied to claim 20 above, and further in view of Wang et al. (PN 5807520).

a. With regards to claim 22, Kaldany does not the integral forming of a balloon portion.

b. Wang teaches a method for forming a balloon for a catheter from an extruded piece of tubing (abstract). Wang teaches that the balloon catheters formed from this method produce a smaller balloon thickness providing easier insertion into the body (col 11 ln 45-49). It would have been obvious for one of ordinary skill in the art at the time the invention was made to use a portion of the catheter produced by Kaldany for a balloon as taught by Wang, because doing so results in an improved balloon catheter.

c. With regards to claim 23, Wang teaches applying heat and pressure to shape the balloon (col 8 ln 16-60).

11. Claims 26, 39, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaldany (PN 5222949) in view of O'Neil et al. (PN 5998551) and Lai (PN 5310779).

a. With regards to claim 26, 39, and 40, Kaldany teaches a method of forming a catheter with varying durometer (abstract) continuously formed by subjecting portions of the catheter to radiation (col 5 ln 1-6) after extrusion (col 5 ln 25-30). Kaldany does not teach a polyamide material or an interior tubular element.

b. O'Neil teaches a nylon block copolymer of polyamide and elastomer that cross links when subjected to irradiation, which improves mechanical properties, useful in the medical industry (abstract). O'Neil teaches the formation of a catheter with varying durometer through the irradiation (col 4 ln 35-42). O'Neil teaches the inclusion of a cross linking promoter of triallylcyanurate (TAC) or triallylisocyanurate (TAIC) in an amount of 2% by weight (col 4 ln 15-17, col 3 ln 38-41). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the nylon block copolymer of O'Neil in the process of Kaldany, because both relate to the formation of varying durometer catheters and O'Neil teaches that the material is advantageous for rigid/flex catheters (col 4 ln 49-55).

c. Lai teaches that known cross linking agents include triallyl cyanurate and diallyl phthalate (col 2 ln 11-12). It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the cross linking agent of O'Neil for an equivalent cross linking agent such as diallyl phthalate as such are art recognized equivalents presenting a reasonable expectation of success.

12. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaldany (PN 5222949) in view of O'Neil et al. (PN 5998551) and Lai (PN 5310779) as applied to claim 26, and further in view of Chromecek et al. (PN 4436887).

a. With regards to claim 27, Kaldany in view of O'Neil and Lai as applied to claim 26 above teach a method for making a catheter from a polyether amide containing nylon in which a cross linking agent is included such as diallyl phthalate.

b. Chromecek teaches several equivalent cross linking agents for use in polylactam copolymer cross linking including diallyl phthalate, diallyl maleate, and triallyl isocyanurate (col 7 ln 43-68, col 2 ln 25-35). It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. Therefor it would have been obvious to one of ordinary skill in the art at the time the invention was made to include mixtures of known cross linking agents such as diallyl phthalate and diallyl maleate as they serve the same purpose and are known equivalent cross linking agents.

Allowable Subject Matter

13. Claims 17, 19, and 36 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

14. The following is a statement of reasons for the indication of allowable subject matter: The prior art of record does not teach nor render obvious the use of a shield of varying density between a radiation source and a catheter composed of polyether amide to form a catheter with varying degrees of cross linking. The prior art of record also does not teach nor render obvious to use of a cross linking compound consisting of 1, 3, 5 triethyl benzene, 1, 2, 4 triethyl benzene, and 1, 3, 5 triisopropyl benzene in a polyether amide catheter of varying durometer.

Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GALEN HAUTH whose telephone number is (571)270-5516. The examiner can normally be reached on Monday to Thursday 8:30am-5:00pm ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Johnson can be reached on (571)272-1176. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/GHH/

/Christina Johnson/
Supervisory Patent Examiner, Art Unit 1791